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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,268	06/22/2001	Pananchukunath Manoj Kumar	RLL-178US	8724

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,268	KUMAR ET AL.	
	Examin r	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice: Upon further consideration, the Final Rejection has been withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Munayyer et al (WO 99/62516 hereafter referred to as '516), Ayer et al (USPN 3,980,778 hereafter referred to as '778) and Liversidge et al (USPN 5,145,684 hereafter referred to as '684). Claims 1-9 are drawn to an oral formulation comprising loratadine particles with an average particle size between 0.1 and 15 microns. Claims 10-18 are drawn to a process of making the formulation of claims 1-9 where the drug is milled into a specific particle size.

4. '778 discloses various drug preparations including oral formulation comprising fillers, binders and lubricants. One of the active ingredients can be an antihistamine, where the agents

are ball milled to a size below 5 microns (examples). The formulation establishes continuity between the various dosage forms, and it would be within the level of skill in the art to apply the processing steps of one preparation to those of all preparations. The formulation includes lactose, methylcellulose, starch, and magnesium stearate (col. 11, lin. 44-53). '778 however does not name the specific antihistamine.

5. '516 discloses an oral syrup formulation comprising micronized loratadine in association with fillers, lubricants, and binders (examples). The reference discloses that the loratadine is micronized, yet does not disclose a particular particle size. It would be within the level of skill in the art to ball mill the antihistamine as seen in '778. A skilled artisan would be motivated to do so in order to increase the surface area and in turn affect the bioavailability.

6. As is well established in the art the rate of dissolution of a particle drug can increase with increasing the surface area, i.e. decreasing the particle size (col. 1, lin. 28-30 '684). '684 follows this line of thinking by decreasing the particles size of active agent by various methods including milling (col. 5, lin. 41- col. 6, lin. 56) in order to increase their surface are and in turn their bioavailability. The particles are reduced to 400 nm or 0.4 microns (abstract), and can include antihistamines (col. 3, lin. 68). A skilled artisan would have followed this motivation to mill the micronized particles of '516 as suggested by '778.

7. With regard to the claims recited specific surface areas, it is the position of the examiner that such limitation would be well within the level of skill in the art to determine through routine experimentation. Barring a showing of unexpected results of said particle size/surface are combination, the limitation is deemed non-critical and does not distinguish the claims over the prior art.

8. Therefore one of ordinary skill in the art would have been motivated to reduce the loratadine particles of '516 as shown in '778 and '684 in order to increase the surface area and bioavailability. It would have been obvious to a skilled artisan to combine the teachings and suggestions as such with an expected result of a stable, oral loratadine formulation with increased bioavailability.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005 (after 2/3/04 571-272-0608). The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927 (after 2/3/04 571-272-0602). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600